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EXAMINER
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MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 06/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/786,835

Applicant(s)

FEIX ET AL.

Examiner

Ashwin Mehta

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 3-68 is/are pending in the application.
- 4a) Of the above claim(s) 33 and 68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-32 and 34-67 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 June 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claims 39 and 49 is withdrawn in light of the claim amendments.
3. The rejection of claims 30-32 and 34 under 35 U.S.C. 101 is withdrawn, in light of the claim amendments.
4. The rejections of claims 30-32 and 34-67 under 35 U.S.C. 112, 2<sup>nd</sup> paragraph, are withdrawn in light of the claim amendments.
5. The rejection of claims 30-32, 34-38, 40-48, and 50-66 under 35 U.S.C. 102(b) is withdrawn, in light of the claim amendments.
6. The rejection of claims 30-32 and 33-67 under 35 U.S.C. 103(a) is withdrawn, in light of the claim amendments.

***Election/Restrictions***

7. Applicants are reminded that non-elected and withdrawn claims 33 and 68 require cancellation.

*Claim Rejections - 35 USC § 112*

8. Claims 30-32, and 34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation “which can be used for cloning a root specific nucleic acid sequence” in lines 1-2 of claims 30-32 and 34 renders the claims indefinite. The recitation does not make clear if the sequence is actually being used for cloning or when to use it for cloning. It is suggested that the recitation be removed from the claims.

9. Claims 30-32 and 34-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed 22 October 2002 under item 5. Applicants traverse the rejection in the paper received 21 April 2003. Applicants’ arguments have been fully considered but were not found persuasive.

Applicants argue that the language of the amended claims meets the written description requirement because a concrete description of DNA by way of SEQ ID NOs: 1-7 is present in the claims and the various sequences are disclosed in the sequence listing, and that therefore sequences having more than 70% identity to the various sequences is supported (response, page 14, 1<sup>st</sup> full paragraph). Applicants also argue that the claims further recite that the sequences are

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able to direct a root selective expression of a coding sequence in a plant, and that since the sequence listing discloses the structure, a structure and function are claimed (response, page 14, 2<sup>nd</sup> full paragraph).

However, the only structures having the function of directing root selective expression of coding sequences, shown in the sequence listing are the nucleotide sequences set forth in SEQ ID NOs: 1-7. The specification does not describe the sequences within SEQ ID NOs: 1-7 that are essential to their root-selective transcriptional activity, and the specification does not describe the sequences within SEQ ID NOs: 1-7 that may be changed without affecting their functional activity. The only structures correlated with the function of directing root selective transcription are SEQ ID NOs: 1-7.

10. Claims 30-32 and 34-67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for SEQ ID NOs: 1-7, does not reasonably provide enablement for any nucleic acid sequence that differs from SEQ ID NOs: 1-7 and have root specific transcriptional activity. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims, for the reasons of record stated in the Office action mailed 22 October 2002 under item 6. Applicants traverse the rejection in the paper received 21 April 2003. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue, in response to the citation of Kim et al., that the changes in the nucleotide sequence of Kim et al. occurred in a specific conserved region of 20 nucleotides in the length of the nos promoter wherein the changes resulted in a loss of activity, whereas the

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instantly claimed sequences have identities of more than 70% to various listed sequences, and retain the ability to direct root selective transcription (response, paragraph bridging pages 14-15). However, it is noted that the claims encompass sequences in which much more than 20 nucleotides can be changed. SEQ ID NO: 7, for example, consists of 190 nucleotides, and is the smallest of the sequences set forth in SEQ ID NOs: 1-7. Sequences that have 70% sequence identity to SEQ ID NO: 7 differ in 57 nucleotides, which is much greater than the changes in the 20 nucleotide stretch for the nos promoter pointed out by Applicants. Further, the specification does not provide any guidance as to which 57 nucleotides of SEQ ID NO: 7, or in the other sequences, that can be changed without affecting functional activity.

Applicants also argue that Croy et al. indicates that a modified sequence may be obtained by introducing changes into an unmodified promoter sequence, and that this may be achieved by any appropriate technique (response, page 15, 1<sup>st</sup> full paragraph). However, Croy et al. do not provide any guidance as far as the sequences within instant SEQ ID NOs: 1-7 that can be changed without affecting their activity. It is also noted that Croy et al. do not teach any modifications of the promoter taught in that reference, the extra gene promoter from rape.

Regarding claims 47-57, 59, 63, 64, 66, and 67: Applicants argue that *Agrobacterium tumefaciens* may be used to deliver DNA to yeast and fungi, and submit de Groot et al. (abstract only) and Bundock et al. in support (response, paragraph bridging pages 15-16). However, the issue raised in the last Office action was not whether *Agrobacterium* can be used to transform non-plant cells, but how one would use non-plant host cells comprising the claimed nucleic acid sequences. SEQ ID NOs: 1-7 are plant root-specific promoters. As the sequences would not be

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active in yeast or fungi, it is not clear how one skilled in the art would use SEQ ID NOs: 1-7 to direct transcription of coding sequences operably linked to them in non-plant cells.

Regarding claims 44-46 and 54-56, Applicants argue that the Office misinterpreted the teachings of Walden, and point to a passage in Croy et al. which suggests to them that the presence of only one T-DNA border sequence is sufficient to integrate nucleic acid into the genome in Agrobacterium-mediated transformation (response, page 16, 3<sup>rd</sup> full paragraph). It is noted, however, that while Applicants allege that the Office misinterpreted Walden, Applicants do not address Walden itself. Walden states that the presence of the border sequences is required to both define and delimit the plasmid sequences which are transferred to the plant genome (page 67). Applicants do not explain why they believe that Walden supposedly teaches that only one border sequence is sufficient. Further, the passage pointed out by Applicants in Croy et al. also does not actually explain how only one border sequence is sufficient to transfer and integrate DNA from an Agrobacterium cell to a plant cell genome. Applicants provide no teaching that indicates that a single T-DNA border is sufficient to routinely transfer and integrate a nucleotide sequence of interest in its entirety, into a plant cell genome. It is also noted that while Walden is an article about Agrobacterium-mediated transformation, Croy et al. is not.

### *Summary*

11. Claims 30-32 and 34-67 remain rejected and claims 33 and 68 remain withdrawn from consideration.

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12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).


Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

Any inquiry concerning this or earlier communications from the examiner should be directed to Ashwin Mehta, whose telephone number is 703-306-4540. The examiner can normally be reached on Mondays-Thursdays and alternate Fridays from 8:00 A.M to 5:30 P.M. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 and 703-872-9306 for regular communications and 703-872-9307 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

June 19, 2003

  
ASHWIN D. MEHTA, PH.D  
PATENT EXAMINER